

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/RU96/00364	12/26/96	11/1/96
TITLE OF INVENTION		
Method of Supplementing the Body		
APPLICANT(S) FOR DO/EO/US		
Y.I. UVRU		09/308913

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
 2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
 3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
 4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
 5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
 6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
 7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
 - ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
 - ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Items 11. to 16. below concern other document(s) or information included:
11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
 12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
 13. ☐ A FIRST preliminary amendment.
 - ☐ A SECOND or SUBSEQUENT preliminary amendment.
 14. ☐ A substitute specification.
 15. ☐ A change of power of attorney and/or address letter.
 16. ☐ Other items or information:

international preliminary examination fee paid to USPTO (37 CFR 1.482) \$640.00
international preliminary examination fee paid to USPTO (37 CFR 1.482) \$710.00
international search fee paid to USPTO (37 CFR 1.445(a)(2)).. \$5950.00

international preliminary examination fee (37 CFR 1.482) nor
international search fee (37CFR 1.445(a)(2)) paid to USPTO..... \$90.00

international preliminary examination fee paid to USPTO (37 CFR 1.482)
and all claimant satisfied provisions of PCT Article 33(2)-(4)..... \$590.00

ENTER APPROPRIATE BASIC FEE AMOUNT = \$

percentage of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30
from the earliest claimed priority date (37 CFR 1.492(c)). \$

Number	Number Filed	Number Extra	Rate	
Claims	-20-		X \$22.00	\$
Dependent Claims	-3-		X \$78.00	\$
Independent Claims(s) (if applicable)			+ \$250.00	\$

TOTAL OF ABOVE CALCULATIONS = \$

reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement
also be filed. (Note 37 CFR 1.9, 1.27, 1.28). \$

SUBTOTAL = \$

issuing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
is from the earliest claimed priority date (37 CFR 1.492(n)). + \$

TOTAL NATIONAL FEE = \$

or recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + \$

TOTAL FEES ENCLOSED = \$

Amount to be:	
refunded	\$
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A check in the amount of \$ 485 to cover the above fees is enclosed.

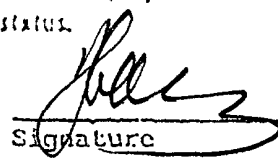
Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. 26-0085. A duplicate copy of this sheet is enclosed.

Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
1.494(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

I. ZBOROVSKY
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Signature

I. ZBOROVSKY
Name

28, 563
REGISTRATION NUMBER

Applicant or Patentee:
Serial or Patent No.
Filed or Issued:
For:

Y.I. Levin

Method of Influencing the Body

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.8 (f) AND 1.27 (b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.8(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled:

Method of Influencing the Body

☒ the specification filed herewith
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.8(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.8(d) or a nonprofit organization under 37 CFR 1.8 (c).

Each person, concern or organization to which I have assigned, granted, conveyed or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below.

☒ no such person, concern, or organization
☐ persons, concerns or organizations listed below

*NOTE. Separate verified statements are required from named person, concern or organization having rights to the invention overing to their status as small entities.
(37 CFR 1.27)

NAME: _____
ADDRESS: _____
☐ individual ☐ small business concern ☐ nonprofit organization

NAME: _____
ADDRESS: _____
☐ individual ☐ small business concern ☐ nonprofit organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as small entity is no longer appropriate. (37 CFR 1.25(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information on belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Yakov I. LEVIN

Full name of sole or first inventor:

First inventor's signature: [Signature]

Date 12.05.99

Residence & Post Office Address:

Citizenship:

Olimpysky Prospect, d.30, kv 301

Moscow 129272, Russian Federation

Russian citizenship

METHOD OF INFLUENCING THE BODY

Field of Technology

The invention relates to the area of medicine and may be used for bioadaptive correction of man's functional condition.

Previous Art

Known from the level of technology are methods of influencing the body by biological feedback, where biopotentials, mainly of brain electrical activity are recorded, transformed and the obtained electroencephalogram (EEG) is processed to isolate, from the spectrum, a certain frequency band that corresponds to alpha-rhythm, and then a control signal is formed generating sound effect on the body with the level proportional to alpha-rhythm in the EEG spectrum (see USSR Authorship Certificate No. 1124922, class A 61 B 5\04, 1984; USSR Authorship Certificate No. 1780716, class A 61 B 5\04, 1992; US Patent No. 3896790, class A 61 B 5\04, 1975).

Psychophysiological effect on man in the above methods, however, is limited by control of alpha activity which does not allow to effectively correct functional condition of the body.

Also known is the method of body functional condition correction with optimization of parameters of external effect on the body which includes recording of physiological parameter biopotentials, transformation and processing of the obtained information with calculation of a biosignal characteristic parameter which is transformed into a control signal, and external effect signals are formed on the basis of the data obtained (see USSR Authorship Certificate No. 1745204, class A 61 B 5\04, 1992).

In this case the external effect, e.g. background sound, is selected from various prerecorded phonograms that differ in volume, rhythm, and tone, using biological feedback to optimize deviation of current characteristic value of the selected biosignal registered during correction of patient's functional condition from the estimated one determined in the preparatory mode. These prerecorded phonograms, however, are of random nature and may not fully correspond to individual features of the body, which reduces effectiveness of man's physiological condition psychophysiological correction by external effect of physical factors, e.g. sound.

Disclosure of the Invention

The invention is aimed at creation of a method to influence the body by means of external physical factor - a sound in the form of a musical tune that adequately reflects man's psychophysiological condition.

Solution of the problem is provided by that the method of influencing the body which includes registration of physiological parameter biopotentials, transformation and processing of the obtained data with calculation of biosignal characteristic generalized parameter, which on the basis of detected criterial correspondence is transformed into a control signal and signals of external sound effect are formed, according to the invention, external sound effect is implemented as generation of musical sounds by parametric variation of their tone, volume, and duration in criterial dependence of variation of value of discrete current generalized parameter of transformed biosignal frequency spectrum, thus from the recorded graphic data isolated are time intervals of identical duration, which are transformed, using the Fourier harmonic analysis, into a

frequency spectrum, then a generalized characteristic dimensionless parameter is determined for each spectral interval, a proportional range of musical sound parameters is formed between minimum and maximum values of the generalized dimensionless parameter, appropriate values of sound tone, volume, and duration are determined for each spectral interval by numerical value of its generalized dimensionless parameter, which are then transformed by a synthesizer into sound signals formed in a sequence that corresponds to initially recorded discrete current alternation of time intervals.

The generalized dimensionless parameter is determined by ratio of power spectral density of at least two characteristic frequency bands isolated in each spectral interval.

A positive outcome of the claimed method is primarily provided by that sound reproduction of physiological activity biosignals is based on the analogy of oscillatory nature of recorded biosignal variation (electroencephalogram - EEG, electrocardiogram - ECG, electrogastrogram - EGG, electromyogram, electroretinogram, pulse wave oscillogram, etc.) and sound oscillatory nature, while suggested criterial dependence between characteristic generalized parameter of frequency spectrum of transformed biosignal and parameters of generated musical sound (tone, volume, and duration) most adequately reflects individual features of man's functional condition and allows to form sequence of sounds in the form of personality music which, if recorded in magnetic medium while the patient is in healthy condition, allows to effectively correct depressive conditions, sleep disturbance, anxiety and other psychophysiological disorders by music therapy.

Brief Description of Drawings

Fig. 1 shows the set of frequency spectra with discrete current alternation of time intervals.

Fig. 2 shows range of musical sound parameters.

The Best Embodiment of the Invention

The method suggested is implemented as follows.

Preliminary, during a satisfactory period of patient's healthy condition, physiological parameter biopotentials, e.g. bioelectric activity of brain, heart muscles, stomach, skeletal muscles, eye retina, pulse waves, etc., are recorded using well-known advanced instrumentation.

Electroencephalogram, EEG, is the most universal and adequately reflects individual functional condition; an example of EEG transformation into the "brain music" is given below.

EEG registered, e.g. within 10 seconds, is divided into equal time intervals of, e.g. 1 second duration; using harmonic analysis, a Fourier expansion, each interval is transformed into frequency spectrum (see Fig. 1). 4 common frequent ranges (Δ , Θ , α , β) are isolated pursuant to the international standard:

$$\Delta = 0.1 - 3.9 \text{ Hz,}$$

$$\Theta = 4.0 - 7.9 \text{ Hz,}$$

$$\alpha = 8.0 - 12.9 \text{ Hz,}$$

$$\beta = 13.0 - 32.0 \text{ Hz,}$$

and a dimensionless generalized characteristic parameter is determined for each spectral interval with respect to power spectral densities of Θ and β intervals, namely:

$$K_1 = P_1 \frac{\Theta}{\beta} = 30.0 = 0.5 \text{ (for 1st second)}$$

$$K_2 = \frac{P_2\Theta}{P_2\beta} = \frac{42.0}{20.0} = 2.1 \text{ (for 2nd second)}$$

$$K_3 = \frac{P_3\Theta}{P_3\beta} = \frac{54.0}{12.0} = 4.5 \text{ (for 3rd second)}$$

$$K_4 = \frac{P_4\Theta}{P_4\beta} = \frac{76.0}{20.0} = 3.8 \text{ (for 4th second)}$$

$$K_5 = \frac{P_5\Theta}{P_5\beta} = \frac{81.4}{11.0} = 7.4 \text{ (for 5th second)}$$

$$K_6 = \frac{P_6\Theta}{P_6\beta} = \frac{105.0}{10.0} = 10.5 \text{ (for 6th second)}$$

$$K_7 = \frac{P_7\Theta}{P_7\beta} = \frac{78.4}{93} = 0.8 \text{ (for 7th second)}$$

$$K_8 = \frac{P_8\Theta}{P_8\beta} = \frac{101.8}{5.5} = 18.5 \text{ (for 8th second)}$$

$$K_9 = \frac{P_9\Theta}{P_9\beta} = \frac{51.0}{8.5} = 6.0 \text{ (for 9th second)}$$

$$K_{10} = \frac{P_{10}\Theta}{P_{10}\beta} = \frac{135.0}{6.0} = 12.5 \text{ (for 10th second),}$$

where K - dimensionless generalized parameter;

$P\Theta$, $P\beta$ - spectral density of characteristic frequency band power ($\text{sq.}\mu\text{V/sec}$).

On the basis of calculation results, determined is a numerical interval between minimum ($K_1 = 0.5$) and maximum ($K_8 = 18.5$) values of generalized characteristic parameter, where drawn is a proportional range of musical sound parameters including 36 notes of three octaves (small, first and second) for piano, 8 volume gradations, and 8 duration segments (see Fig. 2), which reflects criterial relation among them. Numerical value of generalized dimensionless parameter of each spectral interval is used to determine appropriate parameters of musical sound which in the sequence appropriate to originally recorded discrete current alternation of time intervals are transformed (sonified) by means of a sound card (synthesizer) into "brain music" which is recorded on magnetic medium.

The external sound effect - music therapy according to the claimed method was successfully used for treatment of sleep disturbance in over 200 patients as follows.

Patients with sleep disturbance usually have decreased sleep duration, prolonged dormition, increased vigil time inside sleep and increased number of awakenings, increased duration of sleep surface stages (1st and 2nd stages) and decreased delta-sleep and REM duration.

To correct sleep, sleep polygram including electroencephalogram is recorded at satisfactory moment; 2nd stage, delta-sleep and REM sections according to international criteria are selected in EEG, transformed the recorded information pursuant to the claimed method into "brain music", an obtained composition is recorded in magnetic medium. In the process of correction, each patient listens to his/her "brain music" every night in bed for 15 days, which significantly improves subjective characteristic of sleep and objective sleep structure.

Industrial Applicability

Hardware implementation of the method claimed may involve a personal computer with use of advanced electronic instrumentation - electroencephalograph, tape recorder, etc.

CLAIMS

1. The method of influencing the body comprising registration of physiological parameter biopotentials, transformation and processing of the obtained data with calculation of a biosignal characteristic generalized parameter, which on the basis of detected criterial correspondence is transformed into a control signal and forms an external sound effect characterized by that the external sound effect is implemented in the form of generation of musical sounds by parametric variation tone, volume and duration thereof in criterial relation to variation of discrete current values of characteristic generalized parameter of frequency spectrum of the transformed biosignal; isolated from registered graphic information are time intervals of identical duration which are transformed using Fourier harmonic analysis into a frequency spectrum; for each spectral interval a generalized dimensionless parameter is determined; in the numeric interval between minimum and maximum values of spectral interval generalized dimensionless parameter a proportional range of musical sound parameters is formed, for each spectral interval by numerical value of its generalized dimensionless parameter values musical sound parameters are determined and transformed, using a sound card to sound signals which are formed in sequence appropriate to originally recorded discrete current alternation of time intervals.

2. The method of influencing the body according to Claim 1 characterized by that the generalized dimensionless parameter is determined by ratio of power spectral densities of at least two characteristic frequency bands selected in each spectral interval.

ABSTRACT

METHOD OF INFLUENCING THE BODY

The essence of the method is that external sound effect is implemented in the form of generation of musical sounds by parametric variation of their tone, volume, and duration in critical relation to variation of discrete current values of characteristic generalized parameter of transformed biosignal frequency spectrum, a bioelectric potential. From the recorded graphic data on bioelectric activity time intervals of identical duration are isolated and transformed, using the Fourier method, into frequency spectrum; for each spectral interval, generalized dimensionless parameter is determined, in the numerical interval between minimum and maximum values of this parameter a proportional range of musical sound parameters is formed; for each spectral interval, by its generalized parameter numeric values, appropriate parameters of musical sound are determined and transformed, by means of a sound card, to sound signals generated in sequence appropriate to originally recorded alternation of time intervals. The generalized dimensionless parameter may be determined by ratio of power spectral densities of at least two characteristic frequency bands isolated in each spectral interval.

DECLARATION AND POWER OF ATTORNEY FOR NATIONAL STAGE OF PCT PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Method of Influencing the Body the specification of which was filed as PCT International Application number PCT/RU 96/00364 on 12/26/96 and was amended under PCT Article 19 on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56 (a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior foreign application(s)

96121164/14 Russian Federation
(Number) (Country)

11/1/96
Date filed

Priority claimed

Yes _____
Yes No

(Number)

(Country)

Date filed

Yes _____

No

As a named inventor, I hereby appoint the following attorney to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ilya Zborovsky, Reg. No. 28 563

Direct all telephone calls to Ilya Zborovsky at telephone no. 516-2433818 and address all correspondence to:

Ilya Zborovsky
6 Schoolhouse Way
Dix Hills, N.Y. 11746

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Yakov I. LEVIN

First Inventor's signature: _____

Date: 18.05.99

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Citizenship: Russian Federation

Russian Federation RUX

Full name of second inventor: _____

First Inventor's signature: _____

Date: _____

Residence & Post Office Address: _____

Citizenship: _____